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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,199	06/13/2001	Cornelis Theodorius Verrills	PT544(V)	6098
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UNILEVER PATENT DEPARTMENT 45 RIVER ROAD EDGEWATER, NJ 07020				
EXAMINER HENDRICKS, KETH D				
ART UNIT 1761 PAPER NUMBER				

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/880,199	VERRIPS, CORNELIS THEODORUS
Examiner	Art Unit
Keith Hendricks	1761

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' definitions of the terms "probiotic", "health-active" and "[non] viable" are inconsistent both among the responses submitted, and with regard to the prior art. For example, see page 5 of the response of 6-16-03, pages 8-9 of the response of 10-25-02, and applicants' definition at page 6 of the specification.

Applicants' stated claimed invention (from the amendment submitted June 16, 2003) is directed to a composition and method of use, of "probiotic Lactobacillus bacteria which have been rendered non-viable... and wherein no substantial fermentation of the food product by said Lactobacillus bacteria will take place." For the record, applicants have submitted a supportive reference, Guarner et al. (1998) which states that "oral probiotics are living microorganisms", which would correspond to applicants' claims for probiotics which have been rendered non-viable. However, the phrase "wherein no substantial fermentation of the food product by said Lactobacillus bacteria will take place" would appear to conflict with the terms probiotic, and with the knowledge in the prior art.

Reference to Lee et al. (not previously applied in a rejection, but addressed by applicants in the response of 10-25-02, at pages 7-9) shows that bacteria which have been rendered non-viable, are still capable of producing acid from the remaining, existing chemical and enzymatic infrastructure of the microbe, and thus this acid works to ferment the surrounding food product, to a degree. At mid-page 9 of the response of 10-25-02, applicants state that "Lee et al. apparently have no interest, or intention in providing a probiotic effect to the person consuming the food product." Applicants imply that their claimed invention provides a "probiotic effect."

These two positions appear to conflict. Applicants' defined probiotic (i.e. living) bacteria which have been rendered non-viable (i.e. essentially non-living), could not, then, provide a "probiotic effect." Applicant appears to manipulate the definitions of these terms.

It is noted for the record that Lee et al. utilize lactic acid bacteria such as *Pediococcus cerevisiae*, *Streptococcus lactis*, *Lactobacillus acidophilus* and *Lactobacillus plantarum*, each of which was known in the art to be probiotic. Simply because the reference inventors did not address this term as of their filing date 1971, does not mean that these bacteria are/were not probiotic. They are.

Furthermore, it is important to note that the probiotic bacteria rendered non-viable, as taught by Lee et al., do in fact continue to produce acid for a period of time after being rendered non-viable, and this acid participates in fermentation of the food product containing the bacteria. However, applicants appear to be performing the same procedure, and yet claim that "no substantial fermentation" takes place. Applicants do not provide any special or unique means by which this different result is achieved, and in fact appear to simply render the bacteria non-viable as does the reference. Thus it is unclear as to how applicants may claim to arrive at a different result from the known evidence in the art.

Applicant's arguments filed September 16, 2003 have been fully considered but they are not persuasive. At page 2 of the remarks, applicant states that "Lee uses non-viable organisms which had previously been grown until the maximum production of acid forming enzymes is reached, after which the bacterial cells are harvested, packed in suitable containers and made non-viable by irradiation. As indicated in Lee's column 2, in contrast with traditional fermentation procedures, Lee's fermentation does not depend on multiplication of the fermenting organism in the food." Applicant attempts to contrast this with the claimed invention, stating that "since applicant recites a probiotic which has been rendered non-viable, it is not understood why the recitation concerning 'no substantial fermentation' is thought to be inconsistent. Again, Lee's organisms have been grown for maximum production of acid forming enzymes prior to being rendered non-viable."

The recitations are maintained as inconsistent and the invention not sufficiently described in the specification and/or claims, for the reasons of record. Applicant themselves acknowledge that the microorganisms of Lee et al. have (a) been cultured and then rendered non-viable, and yet (b) are still able to ferment the food, due to acid and enzymes produced within the microorganisms prior to being rendered non-viable. This is precisely the point of the examiner, wherein it is unclear as to how applicants may claim that their bacteria, which have been cultured and then rendered non-viable, may then be stated as providing "no substantial fermentation" of the food product. See also page 684, column 2 of Frey et al.

Art Unit: 1761

(of record), which states that "presumably not all cells added are viable, but they will still contribute to enzymatic activity."

Perhaps essential method steps are missing from the instant claims. The amount of acid and enzymes formed by the cultured microorganisms of Lee et al. does not appear to differ from the *claimed* invention, and thus applicant's arguments that these two modes differ, and that the claims are sufficiently described and not inconsistent, are not deemed persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected, as the phrase "health-active" remains indefinite as cited therein, for the reasons of record as set forth at page 2 of the final Office action of January 16, 2003. It is noted that applicants amended certain claims (for example, claims 1, 9-11), but did not amend claim 14, which still contains the phrase. Thus the rejection is maintained.

Claims 21-22 depend from claims 6 and 19, respectively, and both of claims 21-22 recite the limitations "wherein the food product is selected from the group consisting of ice cream, snacks, bars, chocolate and chewing gum". However, there is insufficient antecedent basis for this limitation in the independent claims from which they depend. Neither claim 6 nor 19 recite any of these types of food products. Applicant is also reminded of the rejection previously of record to this point, as found spanning pages 2-3 of the final Office action of January 16, 2003. Furthermore, the contrast between claim 23 and claims 21-22 is noted. (however, claim 23 is grammatically improper for the recitation of "food product is cereal food product.")

Claims 1 and 5-23 are indefinite for the recitation of the phrases "viable", "non-viable", "rendered non-viable" and "said food product being substantially non-fermented by said Lactobacillus bacteria." One skilled in the art would not be reasonably apprised of the metes and bounds of the invention, as stated in the rejection under 35 U.S.C. 112, first paragraph, above. Applicants' definitions of the terms "probiotic", "health-active" and "[non] viable" are inconsistent both among the responses submitted, and with regard to the prior art. For example, see page 5 of the response of 6-16-03, pages 8-9

of the response of 10-25-02, and applicants' definition at page 6 of the specification. The phrase "wherein no substantial fermentation of the food product by said *Lactobacillus* bacteria will take place" would appear to conflict with the terms probiotic, and with the knowledge in the prior art. Furthermore, applicant's defined probiotic (i.e. living) bacteria which have been rendered non-viable (i.e. essentially non-living), could not, then, provide a "probiotic effect." Perhaps essential method steps are missing from the instant claims, amounting to a gap in the claimed method. The confusion may also have to do with applicants' use of the phrase "substantially non-fermented", for which no degree of fermentation – or lack thereof – is set forth. Applicant has not provided a set meaning to these terms which finds basis within the art and within the specification, and has not particularly pointed out and distinctly claimed the subject matter.

Note that this also provides a difficult search of the prior art for potential rejections under 35 U.S.C. 102 or 103.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

i) Claims 1, 5-6, 10-11, 14, 16-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US PAT 3,794,739, of record).

Lee et al. disclose a method of inoculating food with lactic acid-producing bacterial cells, including *Lactobacillus*, which have been previously rendered non-viable. The bacteria still maintain the capacity to produce acid, however, as stated at column 1, "if fermentation is not desired... the inoculated food is cooled to inhibit acid production by the lactic acid bacteria preparation." Acid production can occur, if desired, by subsequent heat treatment of the food product, thus reading upon instant claim 5. "The bacterial preparation is added to the food in amounts equivalent to 10^8 to 10^{10} cells per gram of food" (col. 1). The examples demonstrate the use of the preparation with various meats, including canned ham, vacuum packed turkey and ground beef.

At column 1, it is noted that the culture of live cells is harvested and subsequently mixed with a carrier, such as skim milk. This is then irradiated to render the cells non-viable. As skim milk is also considered a foodstuff (a dairy product, as instantly claimed), the referenced procedure thus reads upon instant claims 14 and 19.

ii) Claims 10-11 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Meister et al. (US PAT 6,010,725).

Meister et al. disclose a process for spray-drying a composition of microorganisms, including *Lactobacillus*, wherein the process is "adjusted so as to obtain survival of at least 1% to 10% or more of the microorganisms after drying" (col. 2). A culture of microorganisms is mixed with a liquid preparation of a food composition, such as milk, or one from meat, fruits or vegetables (col. 4), which is subsequently spray-dried to form a dried food composition containing amounts of both viable and non-viable bacteria. As an example, at column 5 it is stated that the liquid mixture of the process may initially contain 10^8 cfu/g active bacteria, but after drying, only contains 10^6 cfu/g active bacteria. The remainder are rendered non-viable (not active and not alive). The spray-drying process employs temperatures of greater than 200°C , where the final product has a water activity of between about 0.05 and 0.5 (col. 5-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froseth et al. (US PAT 6,592,915) in view of Meister et al., taken as cited above. Note that Froseth et al. qualifies as prior art under 35 U.S.C. 102(e) and thus 35 U.S.C. 103(a).

Froseth et al. disclose the production of layered cereal bars containing ready-to-eat (RTE) cereal, wherein "the basic physical composition of the cereal bar is that of a 'sandwich' composed of two cereal layers with a visible center or middle layer, e.g., a creamy milk-filling layer." The bar may contain various components and additives, where it is stated that

Art Unit: 1761

Additives further include nutrient and health additives such as vitamins, minerals, encapsulated biologically active components, nutraceuticals..., dietary supplements, anti-oxidants, fibers, inulin, calcium carbonate, probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus), energy additives, protein powders, powdered milk fractions, protein or satiety additives, herbs, aromatic substances, and other similar health-enhancing additives. [underlining added]

The use of milk powder in the cereal bar is mentioned throughout Froseth et al.

Thus, it would have been obvious for one of ordinary skill in the art to have utilized the known probiotic bacteria (*Lactobacillus*)-containing powdered milk preparation of Meister et al. within the layered cereal bar of Froseth et al., which contained a "milk-filling layer", and which specifically suggested the use of "probiotic bacteria sprinkles (e.g., lactobacillus or acidophilus)", "powdered milk fractions," "and other similar health-enhancing additives." It would not have involved an inventive step for one skilled in the art to have utilized this known preparation. Thus, the combination of references reads upon the instantly-claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KEITH HENDRICKS
PRIMARY EXAMINER